



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0012]

2013 Assuring Radiation Protection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Devices and Radiological Health (CDRH) radiation protection program. The goal of the 2013 Assuring Radiation Protection will be to coordinate Federal, State, and Tribal activities to achieve effective solutions to present and future radiation control problems. The recipient of this cooperative agreement award will be expected to obtain the States' cooperation and participation on committees and working groups established to deal with individual problems. The recipient will also plan and facilitate an annual meeting and develop and offer educational activities to demonstrate mutually beneficial techniques, procedures, and systems relevant to the mission of assuring radiation protection. The recipient will establish committees, in accordance with Federal statutes and regulations, to address, evaluate, and propose solutions for a wide range of radiation health and protection issues.

Examples of relevant areas already identified to be of interest include, but are not limited to:

(1) The application of x-rays to the healing arts; (2) the application of non-medical ionizing radiation and medical/non-medical non-ionizing radiation; and (3) the control and mitigation of radiation exposure from all sources.

DATES: Important dates are as follows:

1. The application due date is April 1, 2013.
2. The anticipated start date is May 1, 2013.
3. The opening date is [DATE OF PUBLICATION IN THE FEDERAL REGISTER].
4. The expiration date is April 2, 2013.

ADDRESSES: Submit electronic applications to: <http://www.grants.gov/>. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT:

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For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.grants.gov/>.

## SUPPLEMENTARY INFORMATION:

## I. Funding Opportunity Description

RFA-FD-13-002

93.103

A. Background

Since 1968, FDA has taken the lead in working with the Nuclear Regulatory Commission (NRC) and its predecessor organizations, the Environmental Protection Agency (EPA), and the Federal Emergency Management Agency (FEMA), to provide financial support for a forum established to foster the exchange of ideas and information among the States and the Federal Government concerning radiation control. This forum has made it possible for State and Federal Agencies to work together to study existing and potential radiological health problems of mutual interest and to apply their increasingly limited resources with maximum efficiency in seeking ways to address these problems, foster coordination, and provide original views.

Three major mechanisms traditionally have been used to achieve this coordination between State and Federal Agencies:

1. When certain radiation control issues warrant specific consideration, committees and other working groups comprised of representatives of State radiation control programs and liaison members from the concerned Federal Agencies have been formed to evaluate these issues and recommend ways to address them. The recommendations of the committees are evaluated by a central management board and final recommended actions are relayed to the appropriate Federal and State Agencies and Tribal organizations.
2. Annual meetings of Federal and State officials are convened to present and discuss the results of the recommended actions. The annual meetings also include workshops to more carefully

define new problems and areas of mutual concern in radiation control, and clinics to demonstrate mutually beneficial radiological health techniques, procedures, and systems. The annual meeting lasts approximately 4 days, with an average attendance of 350 participants.

3. Additional educational activities have been developed and provided for the benefit of members of State programs having radiation control responsibilities and the general public to acquaint them with radiation exposure problems and the proposed solutions. Methods used have included videotapes, publications, and training courses.

### B. Research Objectives

The objective of this cooperative agreement will be to coordinate Federal, State, and Tribal activities to achieve effective solutions to present and future radiation control problems. The recipient of this cooperative agreement award will be expected to obtain the States' cooperation and participation on committees and working groups established to deal with individual problems. The recipient will also plan and facilitate an annual meeting, and develop and offer educational activities to demonstrate mutually beneficial techniques, procedures, and systems relevant to the mission of assuring radiation protection. The recipient will establish committees, in accordance with Federal statutes and regulations, to address, evaluate, and propose solutions for a wide range of radiation health and protection issues. Examples of relevant areas already identified to be of interest include, but are not limited to: (1) The application of x-rays to the healing arts; (2) the application of non-medical ionizing radiation and medical/non-medical non-ionizing radiation; and (3) the control and mitigation of radiation exposure from all sources. These areas are explained more fully in the following paragraphs.

## 1. Areas of Interest

a. Application of x-rays to the healing arts. The recipient will address issues related to x-rays in the healing arts including issues related to general diagnostic and therapeutic radiology. Issues related to medical imaging (fluoroscopy and computed tomography) and therapy radiography (linear accelerator or source based therapy) should be considered in terms of practice guidelines, quality assurance procedures, and patient exposure evaluation. In the area of patient exposure, the recipient will be responsible for conducting a survey of a representative sample of medical x-ray facilities conducting one specific diagnostic x-ray procedure (from a set of predefined procedures that will be the subject of the survey over time).

b. Application of non-medical ionizing radiation and medical/non-medical non-ionizing radiation. The recipient will address issues in the non-medical applications of ionizing radiation as well as the medical and non-medical applications of non-ionizing radiation.

c. Control and mitigation of radiation exposure. The recipient will be responsible for developing criteria relevant to the control and mitigation of radiation exposure from all sources. Specific areas to be addressed include: (1) Responding to radiation accidents or incidents; (2) evaluating the adequacy of State radiation control programs; overseeing radiation laboratory capabilities; (3) controlling residual radioactivity levels from decontamination and decommissioning of nuclear facilities; (4) determining the propriety of delegating implementation authority for Federal standards for control of radionuclides as hazardous air pollutants; and (5) implementing the Indoor Radon Abatement Act (15 U.S.C 53, Subchapter III). The recipient will also be required to review and provide comments on issues related to radiological emergency preparedness and homeland security.

## 2. Suggested State Regulations for the Control of Radiation (SSRCR)

The recipient of this cooperative agreement award will be expected to provide the leadership to refresh and update previously developed consensus guidance documents and SSRCR to provide States with up-to-date assistance in effective management of radiological hazards.

Updating and maintaining the SSRCR will be an integral aspect of this cooperative agreement. These regulations will be disseminated to the States for the purpose of promoting uniformity between the States. The regulations will address issues relevant to controlling radiation exposure from all sources such as low-level waste, radioactive contamination, radioactive materials, radon, and x-rays in the healing arts.

The recipient will be required to develop a process to determine the need, priority, and timing for regulation updates and development of new SSRCRs. This shall include collaboration with the Federal Agencies, in accordance with Federal statutes and regulations that are providing access to rules that are still under development to enable the recipient to initiate timely development or revisions in parallel.

## 3. Committee Oversight and Management

The recipient should anticipate oversight and management responsibilities for approximately 45 committees. In some instances, the recipient will be required to provide representatives to certain Federal radiation committees, such as the Federal Radiological Preparedness Coordinating Committee and its subcommittees (overseen by FEMA).

While official committee members are limited to State members, non-State and Federal representatives may be appointed as advisors to these committees and other working groups dealing with problems related to the Agency mission. These representatives will participate in

the discussions leading to any recommendations developed by the committees and working groups. They will be primarily responsible for assuring that such recommendations are in accordance with Federal statutes, regulations, and policy. The representatives will also act as investigators, collaborators, or resource personnel, as appropriate.

#### 4. Special Projects

The recipient will implement special projects as determined by the participating State and Federal Agencies. Areas for which groups may be needed include, but are not limited to, radioactive materials and radiation exposure problems in the environment, in the healing arts, in industry, and in, or related to, consumer products. Deliverables may include studies, reports, or recommendations.

#### 5. Annual Meeting/Training

The recipient will be required to plan, conduct, and handle all administrative functions for an annual meeting. This meeting will offer an opportunity for member States and other interested parties to convene to exchange concerns and ideas for problem solving. The recipient should consult with stakeholders to determine priority agenda items and topics of interest. General Sessions of this annual meeting should include workshops to define new problems, and discussions and lectures on mutually beneficial radiological health techniques, procedures, and systems. Identified areas of mutual concern in radiation control should be considered for assignment to a task force or committee comprised of experts. The recipient will be expected to publish the meeting proceedings on the recipient's web site for limited dissemination to member States and relevant Federal personnel.

In conjunction with the annual meeting, the recipient will be required to hold training sessions. These sessions should demonstrate mutually beneficial techniques, procedures, and

systems that have been developed by the sponsoring Agencies or the recipient. The recipient may also be requested by FDA to provide instructors for Federal training courses with a radiological component held outside of the annual meeting.

#### 6. Information Access

A Web site will be maintained by the recipient for the benefit of the States and other interested parties. The FDA Project Officer and other designated Federal personnel will be given complete and full access to all information posted on the site that is relevant to the work supported by FDA and other supporting Agencies. The information and materials posted on the site should be reviewed and updated at regular intervals. Expertise in Web site maintenance and security is required to fulfill this task.

#### 7. Reports and Publications

Reports generated by the task forces, committees, and workshops should include recommendations for the resolution of problem areas as well as cost/benefit evaluations and should be delivered within the time frame determined at the time of assignment. These reports will be reviewed, in accordance with Federal statutes and regulations, by the recipient's governing body before final dissemination to Federal and/or State officials. Any publications supported by Federal funds must include a statement acknowledging Federal support, as well as a disclaimer that the information presented is not necessarily the view of the supporting Agencies.

The recipient will provide a periodic newsletter that will be made available to member States and relevant Federal personnel on the Web site. The newsletter should include updates on projects and programs relevant to the mission of, and supported by, the contributing Federal



Agencies. The FDA Project Officer and liaisons from other Federal Agencies supporting this Agreement will be provided access to secured information on the Web site via passwords.

The recipient will also maintain a directory of personnel responsible for radiological health programs in the member States and Federal Agencies. This directory will be updated annually and published for distribution by the recipient. At least two paper copies of the directory and a non-copyright electronic version will be provided to all contributing Federal Agencies.

### C. Eligibility Information

Nonprofits Other Than Institutions of Higher Education:

- Nonprofits with 501(c)(3) IRS status (other than institutions of higher education).

For-Profit Organizations:

- Small businesses; and
- For-profit organizations (other than small businesses).

Governments:

- State Governments,
- County Governments,
- Indian/Native American Tribal Governments (Federally recognized), and
- U.S. Territory or Possession.

Foreign Institutions:

- Non-domestic (non-U.S.) entities (foreign institutions) are not eligible to apply.
- Non-domestic (non-U.S.) components of U.S. organizations are not eligible to apply.

## II. Award Information/Funds Available

### A. Award Amount

FDA in collaboration with the NRC, the EPA, and FEMA, intends to commit \$400,000 in FY 2013. Only one award will be made.

### B. Length of Support

The length of support will be for up to 5 years. Funding beyond the first year will be noncompetitive and will depend on: (1) Acceptable programmatic performance during the preceding year and (2) the availability of Federal fiscal year funds.

### III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://www.grants.gov/> (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management at <https://www.sam.gov/portal/public/SAM>
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at

[http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found

at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov/>.

Dated: January 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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